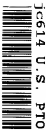


10/02/98



Jc614 U.S. PTO

LAW OFFICES

LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP

600 SOUTH AVENUE WEST

WESTFIELD, NEW JERSEY 07090-1497

(908) 654-5000

FAX: (908) 654-7866

PATENTS, TRADEMARKS AND COPYRIGHTS

October 2, 1998

MICHAEL H. TESCHER
GREGORY S. GEWIRTZ
JONATHAN A. DAVID
SHAWN P. FOLEY
JOHN P. MALDIJAN
THOMAS M. PALISI
STEPHEN F. ROTH
KIMBERLY V. FLUGGER
JASON I. GARBELL
JASON D. SHANSKE
RENEE M. ROBESON
BRIAN K. JOHNSON
LYNNE A. BORCHERS

OF COUNSEL
LAWRENCE I. LERNER
DANIEL H. BOBIS
W. DREW KASTNER

*NORTH CAROLINA BAR ONLY



10/02/98

BOX PATENT APPLICATION
Assistant Commissioner For Patents
Washington, D.C. 20231

File No.: DICO 3.0-006
Inventor(s): Wayne Celia
Title: POLYURETHANE FOAM MATERIALS WITH SKIN CONDITIONING ADDITIVES

Dear Sir:

Enclosed herewith please find the following documents in the above-identified application for Letters Patent of the United States:

1 Pages of Abstract
9 Pages of Specification
14 Number of Claims
0 Sheets of Drawings ☐ A4 ☐ 11"

Unexecuted Declaration
(executed Declaration to follow)
One (1) return-addressed postcard
PLEASE PROVIDE FILING DATE AND SERIAL NUMBER

Please charge Deposit Account No. 12-1095 in the amount of \$1,060.00, calculated as follows:

Basic Fee	\$	790.00
Additional Fees:		
Total number of claims (including multiple dependent claims): 14		
Total number of claims in excess of 20: 0 x \$22		0
Number of independent claims: 3		
Number of independent claims minus 3: 0 x \$82		0
Fee for multiple dependent claim(s) (\$270)		270.00
TOTAL FILING FEE	\$	1,060.00

CONVENTION DATE: for Appln. S.N. is claimed.
Priority Document: ☐ Enclosed ☐ Will follow

In the event the actual fee is greater than the payment authorized above, the Patent Office is authorized to charge any deficiency to our Deposit Account No. 12-1095.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP

DANIEL H. BOBIS, ESQ.

Reg. No. 16,694

LB (LBUNEX) 98022

EXPRESS MAIL LABEL NUMBER:

EM062731985US

POLYURETHANE FOAM MATERIALS WITH SKIN
CONDITIONING ADDITIVES

The invention relates to hydrophilic polyurethane foam
5 pads for the topical treatment and care of the skin. More particularly
the present invention relates to hydrophilic polyurethane foam pads
which contain skin conditioning agents.

BACKGROUND OF THE INVENTION

It has been known to impregnate foam pads with volatile
10 agents for the purpose of slowly releasing these agents over a period of
time. United States Pat. No. 4,339,550, for example, describes a foam
product impregnated with volatile, active materials such as
medicaments, perfumes, deodorants, germicides, pesticides, and
disinfecting and sterilizing agents. The agents are incorporated into the
15 cell structure of hydrophilic polyurethane foam during the foaming
process. However, do to the volatility of these agents, techniques must
be employed to prevent the agents from being rapidly released. These
techniques include using an irreversible chemical reaction which causes
the volatile material to become an intricate part of the foam structure;
20 controlling the pore size of the polyurethane foam structure to permit
only a portion of the volatile material to be released; and using a
variety of controlled release ingredients that aid in producing in a
sustained releases.

It is also known to incorporate nonvolatile agents into
25 foam pads for the care and topical treatment of the skin. United States

09165899-100298

Pat. No. 5,762,946 describes a foam pad having a skin conditioning agent, in powder form, arranged at the center of a sheet of foam. The sheet is superimposed with another sheet such that the powdered product is incorporated between the two sheets. United States Pat. No.

- 5 5,762,946 also describes a foam pad in which the skin conditioning agents are incorporated into the foam pads after the foam has been produced by impregnating the polymerized foam products with a solution containing the skin conditioning agent and then dehydrating the foam product. However, adding the non-volatile agents into the post-
10 polymerization foam structure permits the incorporation of the skin conditioning agents only into the open cell structure of the foam and prevents any substantial retention of the additive or long lasting release benefit.

SUMMARY OF INVENTION

- 15 The present invention is directed to hydrophilic polyurethane foam pads having skin condition agents disposed therein. The hydrophilic foam pads of the present invention are formed from a polymerized combination of an aqueous mixture with a predetermined quantity of hydrophilic urethane prepolymer. The skin conditioning
20 agents are added directly to the prepolymerization aqueous mixture and are thus incorporated directly into the cell structure of the foam pad. The introduction of the skin conditioning additives into the foam matrix

during polymerization produces a foam structure having unique properties such that when wetted, the polyurethane pads quickly will release the skin conditioning agents for application to skin, but will retain a substantial amount of additive for additional application.

5 The present invention is also directed to a method for making a cosmetic pad in accordance with the present invention which includes the steps for forming the composite material by:

 a) metering and mixing an aqueous mixture having at least one skin conditioning agent and adequate water, with a
10 predetermined ratio of hydrophilic urethane prepolymer to provide a polymerizing mixture for forming the foam layer of the composite material;

 b) depositing the polymerizing mixture on releasable bottom paper disposed on a moveable carrier and covering the upper
15 surface of the polymerizing mixture with releasable top paper as the polymerizing mixture is moved with the carrier;

 c) advancing the polymerizing mixture in the top and bottom release paper by moving the carrier and sizing the foam layer being formed to the desired thickness until it is tack free;

20 d) sequentially removing the top and bottom releasable paper and simultaneously drying the sized and formed foam layer to remove residual moisture.

DETAILED DESCRIPTION

09165899.100298

The hydrophilic foam pads of the present invention are formed by polymerizing an aqueous mixture having one or more skin conditioning agents with a predetermined quantity of a hydrophilic urethane prepolymer binder so that the polymerization of the polyurethane foam forms a matrix binder for one or more skin conditioning agents. The skin condition agents are incorporated directly into the cell structure of the foam pads and remain there until the foam pads are wetted or contacted with a sufficient moisture content. Once the pads are wetted or contacted with a sufficient moisture content, the skin conditioning agents are released from the matrix and diffuse toward the surface of the pad for contact with the skin.

The formation of the cosmetic pads in accordance with the present invention is done by metering and mixing an aqueous mixture including adequate water and at least one skin conditioning agent with a predetermined ratio of hydrophilic urethane prepolymer to provide a polymerizing mixture. The aqueous mixture includes water which is present in amounts from about 15 to about 95% by weight. The concentration of the skin conditioning agents in the aqueous phase is from about .5% to about 3.5%.

The skin conditioning agents of the present invention are nonvolatile agents and include vitamins, mineral salts, trace elements,

plant and animal extracts, proteins, enzymes, and other agents which have therapeutic benefits for the skin. By the term "nonvolatile" it is meant that the skin conditioning agents have a high boiling or subliming temperature at normal pressures and thus do not readily evaporate at
5 normal temperatures and pressures.

The skin conditioning agents may first be dispersed into a typical surfactant material in a prepared premix. Surfactants may be used in the aqueous solution to increase the concentration of the skin conditioning agents in the aqueous mixture. The surfactants are
10 preferably present in amounts of about 0.5 to about 3.5 % by weight of the aqueous mixture. The surfactants may be prepared from nonionic polyethylene and polypropylene oxides such as BASF surfactant available under the trademark "PLURONIC". Other components may be added to the aqueous mixture to increase the concentration of the
15 skin conditioning agent, such as citric acid which acts as a buffer for reducing the pH of the water component.

The aqueous mixture may further consist of various combinations of other components without departing from the scope of the present invention, including, for example, soaps, bactericides and
20 fungicides. Bactericides are provided in the commercial marketplace by a myriad of suppliers for controlling bacterial and fungal growth.

One preferred material is supplied by Lauricidin Co. of Galena, Ill 61036, under the trademark "LAURICIDIN".

5 The hydrophilic urethane prepolymer component of the present invention is available in the commercial marketplace. Suitable
10 prepolymers will be readily recognized by those of ordinary skill in the art and are described in prior art U.S. Pat. Nos. 4,137,200; 4,209,605; 3,805,532; 2,999,013 and general procedures for the preparation and formation of such prepolymers can be found in Polyurethane's Chemistry and Technology by J. H. Suanders and K. C. Frisch
15 published by John Wiley & Sons, New York, N. Y., at Vol. XVI Part 2, High Polymer Series, "Foam Systems", pages 7-26, and "Procedures for the Preparation of Polymers", pages 26 et seq. One preferred prepolymer for use in the present invention is Bipol 6 available from Mace Adhesives and Coatings. The hydrophilic
20 urethane prepolymer is present in amount of about 20 to about 50 % by weight of the total composition.

As will be appreciated by those skilled in the art, the cosmetic pads of the present invention can be formed to have any desired thickness and shape. After blending and mixing the combination
25 of the aqueous mixtures and hydrophilic urethane prepolymer, the polymerizing foam pad composition is preferably deposited on a releasable bottom paper on a movable carrier. The upper surface of the

polymerizing composition is then covered with a releasable top paper and advanced along the moveable carrier for sizing of the foam to the desired thickness and until the foam is tack free. The top and bottom releasable paper are sequentially removed. When polymerization is complete, residual water may be driven off by drying the foam in a drying unit at a temperature of about 200 F.

Preferably the foam pads of the present invention have a thickness of about 1 mm to about 40 mm. The foam pad may initially be formed into large blocks which are then cut into any desired shape.

10 EXAMPLES:

Example 1

Ingredients	Percent by Weight
Water	93.06%
Surfactant (BASF F88 Pluronic)	1.58%
Burgess Clay (Wolastinite)	4.15%
Bactericide	.28%
Vitamin E	1.23%

This aqueous mixture was then metered with the hydrophilic prepolymer at a ratio of 2 parts aqueous to 1 part polymer by weight and dispensed onto a moving casting liner. After polymerization, the web is sized and compressed to achieve the target thickness.

Example 2

Ingredients	Percent by Weight
-------------	-------------------

Water	93.06%
Surfactant (BASF F88 Pluronic)	1.58%
Burgess Clay (Wolastinite)	4.15%
Bactericide	.28%
Vitamin A	1.23%

This aqueous mixture was then metered and mixed with a hydrophilic prepolymer in a ratio of 3.2 parts to 1 part by weight. After polymerization the web is sized and compressed to desired thickness.

Example 3

Ingredients	Percent by Weight
Water	92.11%
Surfactant (BASF F88 Pluronic)	1.58%
Surfactant (BASF L62 Pluronic)	1.25%
Burgess Clay (Wolastinite)	4.15%
Bactericide	.28%
Aloe	.93%

This aqueous mixture was then metered and mixed with a hydrophilic prepolymer in a ratio of 2.7 parts to 1 by weight. After polymerization the web is sized and compressed to desired thickness.

The embodiments described above should provide adequate details of the invention. However, it should be noted by those skilled in the art that the disclosures herein are exemplary only and that various other alternatives, adaptations and modifications may be made

within the scope of the present invention. Accordingly, the present invention is not limited by the specific embodiments as illustrated.

09165899.100298

CLAIMS

1. A hydrophilic polyurethane foam composition for use as a pad in the topical treatment of the skin comprising the reaction product of:

an aqueous mixture including water which is present in an amount from about 15 to about 95% by weight of the aqueous mixture and at least one skin conditioning agent present in an amount from about 0.5 to about 3.5% by weight of the aqueous mixture; and

- 10 a hydrophilic polyurethane prepolymer of from about 20 to about 50% by weight of the total composition.

2. The composition of claim 1 wherein the aqueous mixture further includes at least one surfactant present in an amount of from about 0.5 to about 5% by weight of the aqueous mixture.

- 15 3. The composition of claim 1 wherein the skin conditioning agent is selected from the group consisting of vitamins, mineral salts, trace elements, plant extracts, animal extracts, proteins, and enzymes.

4. The composition of claim 1 wherein the skin conditioning agent is vitamin E.

5. The composition of claim 1 wherein the skin conditioning agent is vitamin A.

6. The composition of claim 1 wherein the skin conditioning agent is aloe.

7. The composition of any one of the preceding claims wherein the aqueous mixture further includes one or more additives
5 selected from the group consisting of soaps, bactericides, or fungicides.

8. A method for producing a foam pad having one or more skin conditioning agents comprising the steps of:

a) forming an aqueous mixture having at least one skin conditioning agent and water in a quantity sufficient for the
10 mixture;

b) metering a predetermined amount of hydrophilic urethane prepolymer with said aqueous mixture to form a foam layer of composite material, and

c) converting the foam layer into a desired shape for
15 use.

9. A method for producing foam pads having one or more skin conditioning agents comprising the steps of :

a) metering and mixing an aqueous mixture having at least one skin conditioning agent and adequate water, with a
20 predetermined ratio of hydrophilic urethane prepolymer to provide a polymerizing mixture for forming the foam layer of the composite material;

- b) depositing the polymerizing mixture on releasable bottom paper disposed on a moveable carrier and covering the upper surface of the polymerizing mixture with releasable top paper as the polymerizing mixture is moved with the carrier;
- 5 c). advancing the polymerizing mixture in the top and bottom release paper by moving the carrier and sizing the foam layer being formed to the desired thickness until it is tack free;
- d) sequentially removing the top and bottom releasable paper and simultaneously drying the sized and formed foam
- 10 layer to remove residual moisture.

09158899.100298

ABSTRACT

Polyurethane foam pads for use in the topical care and treatment of the skin are disclosed. The polyurethane pads are formed from a polymerized combination of an aqueous mixture having at least one skin conditioning agent (such as Vitamin E or aloe) and a quantity of hydrophilic urethane prepolymer. The skin conditioning agents are incorporated directly into the cell structure of the polyurethane foam pad and are readily released when contacted with water.

PADOCSTJIG3.0156331.DOC

09165839.100298

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

ATTORNEY'S DOCKET NO.: DICO 3.0-006

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

POLYURETHANE FOAM MATERIALS WITH SKIN CONDITIONING ADDITIVES the specification of which

☒ is attached hereto

☐ was filed on _____ as United States Application Number or PCT International Application Number _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (month, day, year)	PRIORITY CLAIMED
			YES <input type="checkbox"/> NO <input type="checkbox"/>
			YES <input type="checkbox"/> NO <input type="checkbox"/>
			YES <input type="checkbox"/> NO <input type="checkbox"/>
LISTING OF FOREIGN APPLICATIONS CONTINUED ON PAGE 3 HEREOF <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			

I hereby claim the benefit under Title 35, United States Code, § 119(c) of any United States provisional application(s) listed below:

Application Number:

Filing Date:

Application Number:

Filing Date:

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

U.S. Parent Application Serial Number:

Parent Filing Date:

Parent Patent No.:

U.S. Parent Application Serial Number:

Parent Filing Date:

Parent Patent No.:

PCT Parent Number:

Parent Filing Date:

LISTING OF US APPLICATIONS CONTINUED ON PAGE 3 HEREOF: ☐ YES ☒ NO

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Lawrence I. Lerner, Reg. No. 19,516; Sidney David, Reg. No. 22,786; Joseph S. Littenberg, Reg. No. 20,632; Arnold H. Krumholz, Reg. No. 25,426; William L. Mentlik, Reg. No. 27,108; John R. Nelson, Reg. No. 26,673; Roy H. Wegner, Reg. No. 28,550; Stephen B. Goldman, Reg. No. 28,512; Paul H. Kochanski, Reg. No. 28,660; Marcus J. Millet, Reg. No. 28,241; Bruce H. Sales, Reg. No. 32,793; Daniel H. Bobis, Reg. No. 16,664; Keith E. Gilman, Reg. No. 32,137; Robert B. Cohen, Reg. No. 32,768; Arnold B. Dompieri, Reg. No. 29,736; Michael H. Teschner, Reg. No. 32,862; Gregory S. Genswitz, Reg. No. 36,522; Jonathan A. David, Reg. No. 36,494; Shawn P. Foley, Reg. No. 33,071; Thomas M. Pallie, Reg. No. 36,626; John P. Maidjian, Reg. No. 41,967; Renée R. Gilmore, Reg. No. P-41,777.

SEND CORRESPONDENCE TO:
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090

DIRECT TELEPHONE CALLS TO:
(name and telephone number)

DANIEL H. BOBIS, ESQ.
(908) 654-5000 Fax: (908) 654-7866

DECLARATION -- Page 2

ATTORNEY DOCKET NO. DICO 3.0-006

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name): WAYNE CELIA

Inventor's signature _____ Date _____

Residence: Paramus, New Jersey Citizenship: U.S.A.

Post Office Address: 242 Purdue Court, Paramus, New Jersey 07652

Full name of second joint inventor, if any (given name, family name)

Second Inventor's signature _____ Date _____

Residence: _____ Citizenship: _____

Post Office Address: _____

Full name of third joint inventor, if any (given name, family name):

Third Inventor's signature _____ Date _____

Residence: _____ Citizenship: _____

Post Office Address: _____

Full name of fourth joint inventor, if any (given name, family name):

Fourth Inventor's signature _____ Date _____

Residence: _____ Citizenship: _____

Post Office Address: _____

Full name of fifth joint inventor (given name, family name):

Fifth Inventor's signature _____ Date _____

Residence: _____ Citizenship: _____

Post Office Address: _____

Full name of sixth joint inventor, if any (given name, family name):

Sixth Inventor's signature _____ Date _____

Residence: _____ Citizenship: _____

Post Office Address: _____

Full name of seventh joint inventor, if any (given name, family name):

Seventh Inventor's signature _____ Date _____

Residence: _____ Citizenship: _____

Post Office Address: _____

Full name of eighth joint inventor, if any (given name, family name):

Eighth Inventor's signature _____ Date _____

Residence: _____ Citizenship: _____

Post Office Address: _____

☐ Additional inventors are being named on separately numbered sheets attached hereto.